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LONG TERM H.PYLORI ERADICATION AFTER ANTIBIOTIC THERAPY IN DUODENAL ULCER PATIENTS IN CHILE.

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H. pylori (Hp) is a major pathogen involved in gastric inflammation. gastroduodenal ulcers and probably some types of gastric cancer. The early acquisition and lifelong mainteinance of Hp infection is very common in underdeveloped areas of the world.

An adecuate antibiotic regimen is a useful alternative to cure duodenal ulcers, however its implementation in underdeveloped areas has been questioned assuming such individuals had a high re-infection index that invalidate even successful therapeutic assays.

To test the real impact of Hp re-infection in a region with high Hp prevalence we evaluated a group of 60 duodenal ulcer patients from low socio-economic level. who received a triple antibiotic therapy in a Public Santiago Hospital. The 4 weeks therapeutic regimen included omeprazole (20 mg po q24h, 4 wks), amoxicillin (500 mg po q8h), metronidazole (250 mg po q8h) and bismuth subsalicilate (524 mg po q6h). The prospective study included clinical, endoscopic, microbiologic (direct biopsy urease test, microscopy and culture) and serologic (IgG ELISA) evaluations on admission on day 28 and at 4, 8, and 12 mo later.

During a 12 mo follow up study a total of 49/60 (82%) patients healed their ulcers and eradicated Hp infection. According to clinic, endoscopic, bacteriologic and serologic evaluations none of these cured duodenal ulcer patients become re-infected in the following year of observation. The remaining 11/60 (18%) patients all had ulcer healing on day 28th. Among them 4 (36%) never had Hp negative evaluations, five (45%) became re-colonized by month fourth and 2 (18%) were Hp positive after a year. In total only 1/11 (10%) had ulcer recurrences after a year of surveillance.

According to data presented here both eradicated and non eradicated duodenal ulcer patients who received a triple antibiotic therapy had low recuirrence rates. In comparisson patients treated with omeprazole alone (31/4963%). In conclusion triple therapy to cure duodenal ulcers patients constitutes a cost effective intervention even in a highly contaminated environment with high rates of Hp colonization in asymptomatic individuals (1).

1.- G. Figueroa, M. Troncoso, D.P. Portell, M.S. Toledo, R. Acufia, L. Arellano. Eur J Clin Microbiol Infect Dis, 12: 795, 1993.

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EFFICACY OF AMOXYCILLIN COMPARED WITH CLASSICAL TRIPLE THERAPY IN THE ERADICATION OF H.PYLORI AFTER PRE-TREATMENT WITH LANSOPRAZOLE.

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Proton pump inhibitor (PPI) pre-treatment may reduce the eradication rate of H.pylori with some antibiotics. It is,therefore,unclear which eradication regimen is most effective in patients already taking PPIs. We aimed to compare the effects of a lansoprazole (LAN) pre-treatment on the eradicating capacity of two different antibiotic regimens in patients (pts) with duodenal ulcer. 96 pts with HP-positive active duodenal ulcer (59 males),diagnosed by endoscopy, histology and rapid urease test,were randomized to receive one of the following three regimens: LAN 30 mg bid for 4 wks plus amox 1 g tid during the last two wks,LAN 30 mg once daily for 4 wks plus the classical triple therapy (CBS 480 mg,amox 3 g and tinidazole 1 g/daily) during the last 2 wks,or LAN alone (30 mg/day) for 4 wks. Endoscopic healing rates at 4 wks were very high and similar in all the three groups of treatment (96% with LAN+amox,96% with LAN+triple therapy and 97% with LAN alone,respectively). LAN + classical triple regimen was significantly better for HP eradication than high dose LAN and amox (89% versus 55%, p< 0.02),whereas the eradication rate with LAN alone was only of 3%. The frequency of significant side effects was higher with the LAN+triple therapy (10%) than with high dose LAN and amox (3%),although only one patient of the former group stopped therapy due to unwanted effects.
Our findings show that classical triple therapy is more effective than amoxycillin in eradicating H.pylori in duodenal ulcer patients pre-treated with PPIs.

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OMEPRAZOLE PLUS CLARITHROMICIN: EFFICACY OF TWO TREATMENT REGIMENS ON HELICOBACTER PYLORI POSITIVE DUODENAL ULCER

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Eradication of Helicobacter Pylori (HP) infection changes the natural course of duodenal ulcer (DU) and prevent DU relapse. The aim of our study was to compare the efficacy of Omeprazole (OME) with two different doses of Clarithromicin (CLA) in DU healing and HP eradication. We selected 130 DU pts randomly divided into two groups. Group A: 61 pts (39 M - 22 F; mean age 43.6 ± 13.04; range 20 - 70 yrs) were treated with OME 40 mg daily for 4 weeks plus CLA 1.5 g daily for 2 weeks. Group B: 69 pts (48 M - 21 F; mean age 42.6 ± 14.06; range 18 - 74 yrs) were treated with OME 40 mg daily for 4 weeks plus CLA 1 g daily for 2 weeks. All pts were reassessed by endoscopy, histology, culture and CP-test 8 weeks after the end of therapy. Statistical analysis was carried out using Chi-square test. Four pts in Group A and 5 pts in Group B dropped out. Our results showed that 49/57 pts (86%) in the Group A and 56/64 pts (87.5%) in the Group B were eradicated (p= 0.984; n.s.) while 57/57 pts (100%) in the Group A and 61/64 pts (95.3%) in the Group B were healed (p= 0.285; n.s.). Our data demonstrate a similar effectiveness of both treatment. For this reason we prefer OME 40 mg daily plus CLA 1 g daily treatment because patient compliance is good, side effects are nearly absent and the cost is lower.

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DUODENAL ULCER HEALING AND HELICOBACTER PYLORI ERADICATION BY ONE-WEEK LOW-DOSE TRIPLE THERAPY WITH OMEPRAZOLE, CLARITHROMYCIN AND METRONIDAZOLE.

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Aim: The hypothesis was tested that one-week highly effective anti-H.pylori therapy is sufficient to heal H.pylori infection and duodenal ulcers as well.
Methods: 55 patients with active duodenal ulceration and confirmed H.pylori infection by ^{13}C-urea breath test were treated with omeprazole 20 mg bd, clarithromycin 250 mg bd and metronidazole 400 mg bd over one week. During the subsequent 3 weeks patients were treated with either omeprazole 20 mg od or placebo in a double-blind fashion. Ulcer healing was endoscopically checked 2 and 4 weeks after enrollment to the study. Eradication of H.pylori infection was assessed by urea breath test 4 weeks after stopping any study medication.
Results: 52 patients completed the study without contravening the protocol. Two patients were lost to follow-up and another patient stopped study medication because of side effects (mouth burning, diarrhea) after 4 days and withdrew from the trial. Ulcer healing was endoscopically observed in 45 out of 53 patients after two weeks (85%; 95%-CI: 72%-93%) and in all patients (n=53) after 4 weeks (100%; 95%-CI: 93%-100%). H.pylori eradication succeeded in 50 out of 52 patients (96%; 95%-CI: 87%-100%). Adverse events were reported by 7/54 patients (13%; 95%-CI: 5%-25%) that led to discontinuation of the medication in 1 patient (2%; 95%-CI: 0%-10%).
Conclusion: One-week low-dose triple therapy is a highly effective, simple and well tolerated regimen for cure of H.pylori infection and duodenal ulcer healing as well. Commencement of antisecretory drugs beyond the eradication therapy seems to be excessive.

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GR122311X (RANITIDINE BISMUTH CITRATE) WITH AMOXYCILLIN FOR THE ERADICATION OF *HELICOBACTER PYLORI*. C O'Morain[1], TB Schulz[2], C-Y Tam[3], MF Dixon[4], P Quirke[4], AE Duggan[5]. [1]Meath Hospital, Dublin. [2]Aust-Agder Central Hospital, Arendal, Norway. [3]Tuen Mun Hospital, New Territories, Hong Kong. [4]General Infirmary, Leeds, UK. [5]Glaxo Research & Development Ltd, UK.

Introduction: This double-blind, randomised, multicentre study compared the efficacy and safety of GR122311X(GR) 400mg bd monotherapy for 28 days (GR400) to treatment with GR 400mg bd or 800mg bd in co-prescription with amoxycillin 500mg qds for 14 days, followed by 14 days of GR 400mg bd monotherapy (GR400+AMOX and GR800+AMOX, respectively) in the eradication of *Helicobacter pylori(H.p)*. **Patients and Methods:** 98 patients with active DU (93 with confirmed *H.p* infection) entered the study. Patients with healed ulcers had a further endoscopy at least 28 days after the end of treatment. *H.p* was assessed by ^{13}C-urea breath test (UBT), antral and corpus histology (modified Giemsa stain) and antral and corpus CLOtest™ at each endoscopy. In a modified Intent-to-Treat analysis of patients with at least 2 evaluable diagnostic tests, *H.p* eradication was assumed if all tests were negative (6 biopsies and excess $\delta^{13}C0_2$ ≤5 per mil) >4 weeks after the end of treatment. Trough plasma bismuth levels were also assayed.

Results (Intent-to-Treat Analysis)	GR400	GR400 + AMOX	GR800 + AMOX
• Numbers of patients with DU	33	31	34
• *H. pylori* eradication (observed)	0%	48%*	74%*
• Healing rates at 4wk (LOCF)†	76%	77%	91%
• Patients with any adverse event	24%	20%	12%
• Median 4wk plasma bismuth (ng/mL)	2.1	1.9	2.7

*p<0.001 for comparison of monotherapy with each co-prescription regimen.
†LOCF = last observation carried forward

Good concordance was observed between *H.p* diagnostic tests for individual patients. Corpus biopsies did not appear to increase the post-treatment sensitivity of the histology or CLOtest with these regimens.

Conclusion GR in co-prescription with amoxycillin was significantly more effective for the eradication of *H. pylori* than monotherapy. All regimens were well tolerated and effective in the healing of DU.

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GR122311X (RANITIDINE BISMUTH CITRATE) WITH CLARITHROMYCIN FOR THE ERADICATION OF *HELICOBACTER PYLORI*. RE Pounder[1], R Bailey[2], JA Louw[3], B Ohlin[4] MF Dixon[5], P Quirke[5], AE Duggan[6] [1]Royal Free Hospital, UK. [2]Edmonton, Canada. [3]Groote Schuur Hospital, Cape Town, South Africa. [4]Centralsjukhuset, Karlskrona, Sweden. [5]General Infirmary, Leeds, UK. [6]Glaxo Research and Development Limited, UK.

Introduction: This double-blind, randomised, multicentre study compared the efficacy and safety of GR122311X (GR) 400mg bd monotherapy for 28 days (GR400) to treatment with GR 400mg bd or 800mg bd in co-prescription with clarithromycin 250mg qds for 14 days, followed by 14 days of GR 400mg bd monotherapy (GR400+CLAR and GR800+CLAR, respectively) in *Helicobacter pylori* (*H.p*) eradication. **Patients and Methods:** 95 patients with active DU (91 with confirmed *H.p* infection) entered the study. Patients with healed ulcers had a further endoscopy at least 28 days after the end of treatment. *H.p* was assessed by ^{13}C-urea breath test (UBT), antral and corpus histology (modified Giemsa stain) and CLOtest™ on 2 antral and corpus biopsies at each endoscopy. In a modified Intent-to-Treat analysis of patients who had at least 2 evaluable diagnostic tests, *H.p* eradication was assumed if all tests performed were negative (6 biopsies and excess $\delta^{13}C0_2$ ≤5 per mil) >4 weeks after the end of treatment. Trough plasma bismuth levels were also assayed.

Results (Intent-to-Treat Analysis)	GR400	GR400 + CLAR	GR800 + CLAR
• Numbers of patients with DU	31	32	32
• *H. pylori* eradication (observed)	0%	82%*	74%*
• Healing rates at 4wk (LOCF)†	71%	88%	88%
• Patients with any adverse event	23%	31%	35%
• Median 4wk plasma bismuth (ng/mL)	1.9	7.7	5.8

*p<0.001 for comparison of monotherapy with each co-prescription regimen.
†LOCF = last observation carried forward

Good concordance was observed between *H.p* diagnostic tests for individual patients. Corpus biopsies did not appear to increase the post-treatment sensitivity of the histology or CLOtest with these regimens.

Conclusion GR in co-prescription with clarithromycin was significantly more effective for the eradication of *H. pylori* than monotherapy. All regimens were well tolerated and effective in the healing of DU.

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THE TREATMENT OF DUODENAL ULCER WITH GR122311X (RANITIDINE BISMUTH CITRATE) AND AMOXYCILLIN. E Butruk[1], CK Ching[2], K Schütze[3], AE Duggan[4] [1]Department of Gastroenterology, Institute of Oncology, Poland. [2]Queen Mary Hospital, Hong Kong. [3]Endoscopy Hannuschkrankenhaus, Austria. [4]Glaxo Research and Development Limited, UK.

Introduction: This double-blind, randomised, multicentre study compared the efficacy and safety of GR122311X(GR) 400 mg bd monotherapy for 28 days (GR400) to GR 400mg bd or 800mg bd in co-prescription with amoxycillin 500mg qds for 14 days, followed by 14 days of GR 400mg bd monotherapy (GR400+AMOX and GR800+AMOX), respectively in duodenal ulcer (DU) treatment. **Patients and Methods:** 264 patients with active DU (252 with confirmed *Helicobacter pylori* (*H.p*) infection) entered the study. Patients with healed ulcers were followed for up to 6 months on no therapy with endoscopy at 1, 3 and 6 months. The primary efficacy assessment, overall success rate, was defined as the proportion of patients whose ulcers were healed and who remained ulcer-free during follow-up. *H.p* was assessed by ^{13}C-urea breath test (UBT) and antral and corpus CLOtest™ at each endoscopy. In a modified Intent-to-Treat analysis of patients with both CLOtest and UBT results, *H.p* eradication was assumed if all tests were negative (4 biopsies and excess $\delta^{13}C0_2$ ≤5 per mil) >4 weeks after the end of treatment.

Results (Intent-to-Treat Analysis)	GR400	GR400 + AMOX	GR800 + AMOX
• Numbers of patients with DU	86	89	89
• Overall success rates after 6m follow-up (life-table estimates)	33%	80%*	78%*
• Healing rates at 4wk (LOCF)†	90%	88%	84%
• Relapse rates after 6m (LOCF)†	57%	13%*	14%*
• *H. pylori* eradication (observed)	5%	61%*	68%*
• Patients with any adverse event	17%	19%	24%

*p<0.001 for comparison of monotherapy with each co-prescription regimen.
†LOCF = last observation carried forward

Conclusion The dual therapy was well tolerated and effective in healing of DU, eradication of *H. pylori* (up to 68%) and prevention of DU recurrence for up to 6 months. It had significant advantages over monotherapy.

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RANITIDINE VS OMEPRAZOLE: SHORT-TERM TRIPLE THERAPY IN PATIENTS WITH HELICOBACTER PYLORI POSITIVE DUODENAL ULCER.

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Introduction: The rationale for combined antisecretory and antibacterial treatment of duodenal ulcer is based on the advisability of combining the routine antisecretory therapy, which is highly effective but associated with a high recurrence rate, with eradication of *Helicobacter Pylori* (HP) which appears to minimize recurrence of the lesion.

The aim of the study was to compare the overall therapeutic efficacy of two triple therapy regimens, each using the same two antibacterial agents (clarythromycin and tinidazole), but with different antisecretory agent(ranitidine or omeprazole), in patients with active duodenal ulcer and HP infection.

Methods: The patient population of this prospective open study comprised 100 patients (54 males, 46 females; age range: 21-70 yrs), with active duodenal ulcer and evidence of gastric HP infection (CP-test + histological search in biopsy specimens from the antrum and corpus).

Fifty patients (group A) were randomised to omeprazole 20 mg BD + clarythromycin 250 mg BID + tinidazole 500 mg BID for 7 days and then with omeprazole 20 mg/day for another 3 weeks. The other 50 patients (group B) were randomly allocated to treatment with ranitidine 300 mg BID + clarytromycin and tinidazole for 7 days(at the same doses of the omeprazole containing regimen), and then ranitidine 300 mg/day for another 3 weeks.

The two groups appeared to be well matched for sex, age, characteristics of lesions and clinical history of the disease treated.

Results: At least 2 months after discontinuation of the antisecretory drug a follow-up endoscopy was performed, revealing healing of the duodenal mucosal lesions in all patients. The histological investigation (with haematoxylin-eosin and Giemsa stains) on multiple biopsy specimens from the gastric antrum and corpus revealed eradication of HP in 92% (46/50) patients in group A and in 86% (43/50) patients in group B.(N.S. at Chi-Square test).

Conclusions: The study data revealed no significant differences in terms of tolerability, compliance, healing rates and HP eradication in the two patient groups. Since the two therapeutic regimens differ only in the choise of antisecretory agent, the authors take the view that the clinical experience reported, though requiring future confirmation, appears to demonstrate that ranitidine is equally effective as omeprazole in achieving high HP eradication rates in triple therapy.

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THE SAFETY OF DUAL THERAPY WITH CLARITHROMYCIN AND OMEPRAZOLE IN THE TREATMENT OF PATIENTS WITH DUODENAL ULCER DISEASE ASSOCIATED WITH *H. PYLORI* INFECTION.

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Clarithromycin (CL) was administered in combination with omeprazole (OM) in four large, well-controlled studies (two European and two U.S.) to assess the safety and efficacy of this combination in the eradication of *H. pylori* from the gastric mucosa and prevention of duodenal ulcer recurrence. A total of 346 patients received CL 500 mg TID and OM 40 mg QD for the first 14 days, followed by OM 40 mg QD (in one study) or 20 mg QD (in three studies) for an additional 14 days.

Most Frequently Reported Adverse Events*
(Excluding Taste Perversion)

COSTART Term	All Adverse Events		Excluding Concurrent Conditions	
Nausea	18	(5%)	11	(3%)
Headache	16	(5%)	6	(2%)
Diarrhea	15	(4%)	12	(3%)
Vomiting	12	(3%)	5	(1%)
Abdominal Pain	11	(3%)	8	(2%)
Infection	9	(3%)	1	(<1%)
Total@	142	(41%)	74	(21%)

* Number of patients reporting each adverse event.
@ Number of patients experienced at least one adverse event.

Taste perversion, an adverse event commonly observed throughout the development of CL, was reported by 54 of the 346 patients (15%).
The percentage of CL+OM treated patients reporting adverse events in the U.S. studies (49%, 81/164) and European studies (41%, 75/182) were similar, (p=0.131).
Twelve (3%) of the 346 patients were prematurely terminated from study drug therapy due to adverse events.
For each laboratory parameter, less than one percent (<1%) of the patients had laboratory values considered possibly clinically significant per criteria developed by Abbott Laboratories.
Overall, clarithromycin 500 mg TID in combination with omeprazole 40 mg QD is safe and well tolerated.

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COMPARISON OF TWO LOW DOSE ONE-WEEK TRIPLE THERAPY REGIMENS WITH AND WITHOUT METRONIDAZOLE FOR CURE OF H. PYLORI INFECTION

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Purpose: We have recently shown that a one-week triple therapy consisting of omeprazole 20 mg bid, Clarythromycin 250 mg bid and tinidazole 500 mg bid is very effective with a eradieradication rate of 93%.We therefore investigated a similar regimen consisting of lanzoprazole 30 mg bid, clarythromycin 250 mg and metronidazole 400 mg bid or tetracycline 300 mg bid in a prospective cohort study.

Methods: Two cohorts each of 60 patients, suffering from H.pylori infection associated with peptic ulcer disease or ulcer like dyspepsia were treated for one week with either lanzoprazole 30 mg bid, clarythromycin 250 mg bid and metronidazole 400 mg bid (Cohort I, n=60) or tetracycline 300 mg bid (Cohort II, n=60). H.pylori infection and under-laying disease was diagnosed by endoscopy using rapid urease test and histology. 4 weeks after treatment withdrawal cure of H.pylori was evaluated by using the same criteria as mentioned above.

Results: Patients in the two cohorts had similar clinical and demographic characteristics. In cohort I, 55 patients out of 60 showed cure of H.pylori infection (92%). The treatment was well tolerated. Three patients reported sideeffects, two experienced limited diarrhea and one bad taste. In cohort II, which was free of metronidazole, the eradikation of H.pylori was slightly less effective as only 50 out of 60 showed cure of H.pylori infection (83%). Two patients reported limited diarrhea. The difference between the cohorts of H.pylori eradikation was statistically not significant.

Conclusions: Triple therapy for one week with lanzoprazole as the antisecretory part, seems to be as effective as what is reported for omeprazole. Substitution of metronidazole by tetracycline is somewhat less effective but gives still a high eradikation rate and could be an alternative to patients with metronidazole resistance.

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HEALING OF PEPTIC ULCERS BY CURING HELICOBACTER PYLORI INFECTION.

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Aim: We tested the hypothesis that one-week effective eradication therapy is sufficient to heal H.pylori associated duodenal and gastric ulcers.

Methods: In 4 consecutive prospective studies, 112 patients with endoscopically proven H.pylori positive (culture and/or histology) duodenal ulcers (n=78), gastric ulcers (n=28), or gastroduodenal double ulcers (n=6) were treated with one-week triple therapy schedules consisting of omeprazole 20 mg od, clarithromycin 250 mg bd, and metronidazole 400 mg bd or tetracycline 500 mg bd (OCM, OCT), or with omeprazole 20 mg bd, amoxicillin 1 g bd, and clarithromycin 250 mg bd or metronidazole 400 mg bd (OAC, OAM). Ulcer healing and H.pylori eradication (urease test, culture, histology) were assessed 4 weeks after cessation of the eradication therapy.

Results: In all patients, symptoms referable to ulcer disease disappeared within one week of treatment. The overall 5-week ulcer healing rate was 94.6% (106/112 patients; 95%-CI: 89%-98%). Out of the patients with healed ulcers, 96 have also cured their infection. Ulcer healing was more frequently observed in patients with cure of H.pylori infection as opposed to the group of patients with posttherapeutically persisting bacterial colonization (97% vs 77%; p=0.02). Incomplete ulcer healing after 5 weeks was associated with either persistant H.pylori infection (n=2), intake of Aspirin/NSAIDs (n=3), or treatment with Aspirin (100 mg) and H.pylori persistance (n=1).

Conclusion: In the absence of concomitant treatment with ulcerogenic drugs, a one-week highly effective eradication therapy is sufficient to heal almost all duodenal and gastric ulcers. Thus, prescription of antiulcer drugs beyond eradication therapy seems actually to be excessive.

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ONE-WEEK TREATMENT WITH OMEPRAZOLE, AMOXICILLIN AND CLARITHROMYCIN OR METRONIDAZOLE FOR CURE OF HELICOBACTER PYLORI INFECTION.

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Aim: The present study was conducted to evaluate the efficacy and tolerability of two simple one-week triple therapy schedules for eradication of H.pylori.

Methods: 120 consecutive patients suffering from histologically and/or culturally proven H.pylori infection and associated peptic ulcer disease (duodenal ulcer: n=69; gastric ulcer: n=21; duodenal and gastric ulcer: n=3) or functional dyspepsia (n=30) were recruited. Patients 1-60 were treated with omeprazole 20 mg bd, amoxicillin 1 g bd and clarithromycin 250 mg bd over one week (OAC). Patients 61-120 were treated with omeprazole 20 mg bd, amoxicillin 1 g bd and metronidazole 400 mg bd over one week (OAM). Patients were endoscopically reinvestigated 4 weeks after cessation of eradication therapy including the assessment of the H.pylori status by means of an urease test, culture and histology.

Results: Three patients (OAC: n=1; OAM: n=2) were lost to follow-up. H.pylori infection was eradicated in 53 out of 60 patients of the OAC group (rate (intention-to-treat): 88%; 95%-CI: 77%-95%) and in 47 out of 60 patients of the OAM group (rate: 78%; 95%-CI: 66%-88%) [OAC vs OAM: p=0.22]. Nine patients of either group complained of side effects without necessity of discontinuation of the study medication (rates: 15% vs 15.5%; p=1.00).

Conclusion: One-week simple (bd regimen) triple therapies consisting of omeprazole, amoxicillin and either clarithromycin or metronidazole represent a sufficiently effective and well tolerated approach to the cure of H.pylori infection. In view of a 10% higher efficacy and a markedly lower rate of primary resistance of H.pylori to clarithromycin as to metronidazole, the OAC regimen should be preferred.